COOK®

Cook Group Incorporated

November 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket Number 990-2873

Dear Sir or Madam:

This comment is filed on behalf of the Cook Group, Inc. ("Cook"), a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gastroenterology, emergency medicine and surgery. Cook pioneered the development of products used in the Seldinger technique of angiography, and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention without the necessity of invasive surgery. Cook sells over 15,000 different products which can be purchased in 130,000 combinations.

We welcome the opportunity to comment on the Food and Drug Administration's (FDA), "Draft Guidance on Evidence Models for the Least Burdensome Means to Market." We believe that the concept of "least burdensome" was one of the key features of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The goal of FDAMA was to streamline and allow flexibility in the regulatory approval process so that products could be brought to patients more promptly. We believe that appropriately implementing least burdensome and applying it to all agency clearances is critical to realizing the potential benefits of FDAMA.

In our opinion there are several points that are central to implementing least burdensome:

- The least burdensome concept is best implemented as a process. That process must, as Congress intended, apply to all aspects of all approvals and clearances, i.e., PMAs, PMA supplements and 510(k)s, whether or not they involve clinical data. The process should include steps to:

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1. identify the issues or questions related to substantial equivalence or safety and effectiveness according to the risks and benefits of the device;

2. discriminate between essential and nonessential issues through scientifically sound justification;

3. eliminate nonessential data requirements;

4. establish reasonable methods for obtaining data or information for essential data requirements;

5. resolve disputes regarding the essential determination or methods between FDA and industry in a fair and equitable process.

- Requirements for valid scientific evidence should be confined to answering only those questions that are pertinent and essential. Focused studies are more likely to yield definitive results.

- The purpose of study data should be limited to establishing substantial equivalence or reasonable assurance of safety and effectiveness. The type of data will be specific to the type of device.

- The process must include a method for eliminating nonessential data requirements. The most likely process to succeed is one in which data requirements agreed upon by industry and FDA are consistently accepted by FDA to resolve scientific and medical questions. Data requirements about which industry and FDA disagree should have documented scientifically sound justifications by FDA with similarly supported counter arguments by industry. Documentation should be sufficient to allow an independent party to make judgments based on the scientific merits. Likewise, when a guidance document establishes data requirements, an individual reviewer should provide scientifically sound justification before requesting data beyond the established guidance. Departures from the guidance by industry should (and already do in most cases) require a scientifically sound justification.

- The process should require only essential testing to conserve the resources of FDA and use personnel for more productive efforts.

- The process should recognize that science is developing new, alternative ways to demonstrate safety and effectiveness, such as engineering models, and it should include the flexibility to permit the Agency to apply the best science given the risk and benefits to the particular patient population.

We are very grateful for the opportunity to submit these comments on this very important issue. We should note that the Cook Group was a member of the Medical

Device Industry's "Least Burdensome Task Force." We endorse the comments of the task force that have been filed. We have tried not to reiterate what was in that document, but rather to emphasize the points we believe are most important.

Respectfully,

Stephen L. Ferguson

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